Comments from the United States on the OIE's proposed changes to the Code Chapter on Bovine Spongiform Encephalopathy December 2003 Report of the Terrestrial Animal Health Standards Commission

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The United States is submitting comments to the OIE related to the BSE Chapter in two sections. In Section I we provide comments on the proposed changes to the revised Code Chapter on BSE resulting from the Code Commission's December 2003 meeting. In Section II, we present the Code Commission with a set of criteria that the Commission may use to develop a more simplified system for classifying countries for BSE.

SECTION I
Comments on proposed changes to the current Chapter 2.3.13 - BSE

Article 2.3.13.1 – The United States agrees with the proposed reorganization of the Chapter to highlight first and foremost, the commodities that can be safely traded between countries regardless of the BSE risk, and continue to encourage the OIE to remind Member countries to use the Code Chapter as the basis for establishing import measures for the safe trade of animal and animal products.

However, the draft revision now proposes that "tallow and tallow derivatives, and dicalcium phosphate" can be "safely traded - subject to the prescribed conditions relating to the BSE status of the cattle population of the *exporting* country or zone". Furthermore, Articles 2.3.13.21 and 2.3.13.22 of the proposed revision deletes the words "other than protein-free tallow as defined in Article 2.3.13.8". The United States asks the OIE to provide the documented science for this proposed change. The United States asks that the OIE re-instate protein-free tallow (defined as tallow containing a maximum level of impurities of 0.15% in weight) as a commodity that can be safely traded without BSE related restrictions and regardless of the BSE status of the country. Therefore, protein-free tallow would become item 1) e) under the new Article 2.3.13.1 of the proposed draft, and point d) of Article 2.3.13.1 2) would then be deleted. In addition, the United States asks that that the text "(other than protein-free tallow as defined in Article 2.3.13.8" – and would now be Article 2.3.13.1 in the updated revision) to be re-instated into Articles 2.3.13.21 and 2.3.13.22.

This standard as it currently exists enjoys widespread international support and use, is accepted by all Member countries, and is supported by science. Epidemiological studies have failed to find any association between the occurrence of BSE and the consumption of tallow by cattle. Also, the BSE-spiked rendering studies show no infectivity in crude unfiltered tallow produced by a rendering procedure that produced meat-and-bone meal with almost as much infectivity as was present in the untreated spiked materials.

Finally, we would like the OIE to consider adding blood, blood by-products (dried beef powder, extracts, etc.) and products derived from beef blood to be on this list of commodities that can be safely traded. We have found no scientific data showing blood

is a risk for BSE. While the prion can be found in the blood, scientific evidence points to the extremely low quantities of the agent in blood.

References

Taylor, D.M., Woodgate, S.L. OIE 2003. Rendering Practices and Inactivation of Transmissible Spongiform Encephalopathy Agents. pp. 297-310.

Taylor D.M., Inactivation of BSE-Like Agents, United States Animal Health Association (USAHA) Proceedings, 2001.

European Fat Processors and Renderers Association, The Standing Technical Group of EFPRA, Note on the Safety of Tallow, May 3, 2001.

NRA Issue Update. BSE and the Safety of Tallow, June 2003.

Article 2.3.13.2 – it is proposed to delete point 1, however part d) "epidemiological situation concerning all animal TSE in the country or zone" is not being deleted when the rest of the section is deleted. This may have been an oversight in formatting the revised draft. The United States suggests that it be deleted. Also, under Point 1) a) iv), it may be useful to identify what products of animal origin for human consumption that are of risk. A given product is either a risk or is not a risk, regardless of its proposed use.

Article 2.3.13.8 – The United States agrees with deleting this article and highlighting the safe trade possibilities at the beginning of the Chapter. If this article is deleted, then there is a need to renumber the remaining articles in the Chapter.

Article 2.3.13.16 (renumbered to 2.3.13.15) – part 5) – The United States agrees with the concept of the changes recommended to refer to the Article listing the specified risk materials. We recommend referring to Points 1) and 2) of Article 2.3.13.19 (renumbered to 2.3.13.18) as both points 1) and 2) deal with moderate risk categories and what specified risk materials should be removed.

Article 2.3.13.17 (renumbered to 2.3.13.16) – part 2) – The United States agrees with the concept of the changes recommended to refer to the Article listing the specified risk materials. We recommend referring to Points 1) and 2) of Article 2.3.13.19 (renumbered to 2.3.13.18) as both points 1) and 2) deal with high risk categories and what specified risk materials should be removed.

Article 2.3.13.17 (renumbered to 2.3.13.16) – part 4) - Because of the insertion of a new point 1) in Article 2.3.13.19 (renumbered to 2.3.13.18), this reference needs to be changed so it would read, "…tissues listed in point 2) of Article 2.3.13.19 (renumbered to 2.3.13.18)…"

Article 2.3.13.19 (renumbered to 2.3.13.18) - part 1) – The United States disagrees with the proposed change to require the removal of "intestine" from all cattle from a moderate or high BSE risk country. We question the science the OIE is using to make the decision to remove the entire "intestine" rather than only the distal ileum which is known by scientific evidence to be a material of high risk.

The agent has been documented to have been found in certain lympho-reticular system tissues called the Peyer's patches, which are concentrated in the distal ileum of the small intestine (Wells et. al., 1994). Current research indicates that the infective agent is not found in other gastro-intestinal tissues other than the distal ileum (Wells et al., 1998). Specifically, research has shown that the infective agent is not present in the duodenum and the jejunum portions of the small intestine even when the agent is found in the ileum (Terry et al., 2003). Additionally, the infective agent for BSE has only been found in the distal ileum of cattle which were inoculated with the BSE infective agent; due to the increased amount of infective agent the animals were exposed to; the agent has not been reported to have been found in animals which have succumbed to the disease naturally (Wells et al., 1998; Terry et al., 2003).

Therefore, the United States recommends that "intestine" be deleted and replaced with "distal ileum" so the sentence would read, "…tonsils and distal ileum, and protein…" This will allow Member Countries to make the regulatory decision to ensure complete removal of the distal ileum either by an established protocol or by requiring the removal of the "intestine."

References

Terry, L. A., Marsh, S., Ryder, S. J., Hawkins, S. A. C., Wells, G. A. H., Spencer. Y. I., 2003; Detection of disease-specific PrP in the distal ileum of cattle exposed orally to the agent of bovine spongiform encephalopathy. The Veterinary Record; 152, pages 387-392

Wells, G.A.H, Dawson, M., Hawkins, S. A. C., Green, R. B., Dexter, I., Francis, M. E., Simmons, M. M., Austin, A. R., Horigan, M. W., 1994; Infectivity in the ileum of cattle challenged orally with bovine spongiform encephalopathy. The Veterinary Record; 135, pages 40-41

Wells, G. A. H., Hawkins, S. A. C., Green, R. B., Austin, A. R., Dexter, I., Spencer, Y. I., Chaplin, M. J., Stack, M. J., Dawson, M., 1998; Preliminary observations on the pathogenesis of experimental bovine spongiform encephalopathy (BSE): an update. The Veterinary Record; 142, pages 103-106

Article 2.3.13.19 (renumbered to 2.3.13.18) part 2) –The United States agrees with the proposed changes.

Appendix 3.8.4 – Surveillance and Monitoring Systems for BSE – The United States agrees with the proposed changes as they help clarify the need for a surveillance system by all countries, that it must be paired with a risk assessment, and also what subpopulations should be tested and at what levels. The objective should be to continue to improve the text in this Appendix and strive that surveillance methods and testing levels be set according to the risk status of the exporting country and the specific sub-population of animals (e.g., cattle showing central nervous system symptoms, fallen or non-ambulatory stock, animals for emergency slaughter and a percentage of healthy cattle of defined age at slaughter for a defined period of time).

SECTION II

In this section the United States provides the Code Commission with some basic criteria which may help with the development of a more simplified 3 category BSE classification system.

Suggested criteria to be used for a more simplified BSE classification system:

As the Code Chapter currently recommends, the United States continues to believe that the risk status of a country or region be based on the results of a risk assessment which identifies key risk factors and determines the "overall effectiveness" of control and risk mitigation measures in place (i.e., surveillance, import controls, specified risk material removal and feed ban). Thus, the risk status of a given country/region should be based on the effective implementation of mitigation measures against known risk factors for BSE. It is a risk-based approach classification rather than a prevalence-based approach.

1. **Criteria for Defining "Negligible" Risk for BSE**
   The following criteria or factors for defining a BSE "negligible risk" country or region should be considered (these are similar to those already in the revised proposed chapter):

   - conducts a risk assessment to manage any risk identified;
   - maintains a level of surveillance in compliance with the conditions set forth in Appendix 3.8.4
   - whether there have been no cases of BSE or identified cases have been all imported, the conditions of Article 2.3.13.2 points 2) through 5) have been complied with and have been in place for a specified time period
   - addresses the disposition of any affected cattle and associated cohorts

2. **Criteria for Defining "Controlled Risk" Category**
   We recommend the following criteria for defining a BSE "controlled risk" country or region:

Address the elements identified in Item 1 above, and:

1. Maintains, and, in the case of countries or regions where BSE was reported, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent exposure and/or amplification of the disease, including:

- Import restrictions on high risk animals, products and animal feed;
- Surveillance at levels that meet or exceed OIE recommendations; and,
- Ruminant feed ban with evidence of effective compliance.

2. In countries or regions where BSE was reported, an epidemiological investigation was conducted following detection of BSE to confirm adequacy of measures to prevent the further introduction or spread (e.g., tracebacks, traceforward of risk animals, feed or rendered material, investigations to determine likely source of the animal's exposure).

3. In countries or regions where BSE was reported, countries or region took additional measures, following the BSE outbreak or the detection of a new risk factor, based on conclusions of a risk analysis (e.g., SRM removal, increased surveillance, and/or additional import restrictions).

4. In countries or regions where BSE has been reported, annual prevalence as determined through recognized surveillance of mature animals has demonstrated the effectiveness of risk mitigation measures in place.

<u>Import conditions for imports from "controlled" risk countries or regions</u>

The objective is to liberalize the movement of either low risk trade-able products from "controlled" risk countries or regions. (Note: products that can be traded regardless of a country's BSE status have already been identified in Article 2.3.13.1 in the revised Chapter)

We recommend that "controlled risk" countries or regions certify the following:

- Cattle are *animals born after implementation of an effective feed ban;*
- Cattle or cattle products are from *animals which were not fed risk material (MBM, greaves)*;
- Cattle products are from *animals less than 30 months* of age or from animals from which specified risk materials have been removed;
- *Adequate animal identification system* exist to ensure traceability preservation for exported cattle;
- Specified risk materials are removed in a hygienic manner and disposed of at slaughter.

<u>List of trade-able low risk products,</u> particularly muscle meat, with mitigations dependent on the risk status (or category) of the exporting country.

The sanitary measures should be commensurate with the risk identified in the risk assessment. The objective is to avoid overly restrictive measures which may lead producers in countries to hide rather than report disease suspicions. This would result in greater not lesser risk to the international community.

We recommend the following requirements for commodities from "Controlled Risk" regions or countries:

- *Fresh Meat/Products*—allowable from animals less than 30 months of age with certification requirements (e.g., from animals never fed risk material or from animals from which the distal ileum has been hygienically removed; facilities with segregated systems) or from animals over 30 months of age where specified risk materials have been removed in a hygienic manner.